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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,867	02/04/2002	Halle Morton	999710000008	3108

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EXAMINER	
ANDRES, JANET L	
ART UNIT	**PAPER NUMBER**
1646	9

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,867	MORTON ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that, while interferon β and chaperonin 10 are both known in the art, the claims are drawn to combinations of the two. This is not found persuasive because, as stated in the office action of paper no. 6, the two compounds are also known in the art to be useful for the same purpose, inhibition of inflammation. Thus their use in combination would not constitute a special technical feature, as the rationale for combining them already exists in the prior art.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-24 are pending in this application. Claims 12-24 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. The disclosure is objected to because of the following informalities: there is a sequence on p. 19 that lacks a sequence identifying number.

Appropriate correction is required.

The use of the trademarks BETASERON®, BETAFERON®, NUNCLON®, AVONEX®, and REBIF® have been noted in this application (pp. 15, 22, and 34). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morton et al., WO 95/15338,1995, in view of The Interferon Beta Multiple Sclerosis Study Group, Neurology, 1993, vol. 43, pp. 655-661.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Morton et al. teaches on p. 23 that administration of chaperonin 10 to rats suffering from experimental allergic encephalomyelitis (EAE) delayed the onset, modified the features, and prevented the recurrence of the disease (lines 12-16). Morton et al. further teaches that EAE is a model for multiple sclerosis (p. 21, lines 4-8). Morton et al. concludes on p. 26 (lines 7-13), based on these results, that chaperonin 10 would be useful for the treatment of multiple sclerosis. A range of 1-1000 μg/kg is taught to be useful; for the standard 70 kg human, this range would be .07 - 70 mg. Thus, Morton et al. teaches that chaperonin 10 is useful for treatment of multiple

sclerosis, including prevention of relapse (claim 2) and teaches a range encompassing the instantly claimed ranges (claims 8 and 9). Administration by injection (claim 5) is taught on p. 22, line 24.

Morton et al. fails to teach the administration of interferon β. Administration of interferon β by injection to treat multiple sclerosis is taught by The Interferon Beta Multiple Sclerosis Group; levels of 1.6 and 8 MIU, within the ranges specified in claim 10, are taught in table 3, p. 657. Reduced rate of relapse is taught on p. 660, column 1 (claim 2).

Neither Morton et al. nor The Interferon Beta Multiple Sclerosis Group teach particular sequences of administration (claims 3 and 4), oral administration of chaperonin 10 (claim 6), or the particular range of interferon β specified in claim 11. Such modifications, however, are routine expedients in the art. See MPEP §2144.04, reference to In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.); In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955): "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

It would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Morton et al. with The Interferon Beta Multiple Sclerosis Group to administer interferon β and chaperonin 10 to treat multiple sclerosis because each individually was known to be useful for that purpose. The courts have held that:

"It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form a combination that is to be used for the

very same purpose: the idea of combining them flows logically from their having been individually taught in the prior art."

In re Kerkhoven (205 USPQ 1069, CCPA 1980) (MPEP § 2144.06).

Thus, one of ordinary skill would have been motivated to administer the two agents together because, since each individually was known to be useful; thus one of ordinary skill would have expected the combination to be at least as useful.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
August 4, 2003